UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456 CIVIL ACTION: 01-CV-12257-PBS Judge Patti B. Saris
THIS DOCUMENT RELATES TO: *State of Montana v. Abbott Labs., Inc., et al.*, D. Mont. Cause No. CV-02-09-H-DWM *State of Nevada v. American Home Products Corp., et al.*, D. Nev. Cause No. CV-N-02-0202-ECR	

STATE OF MONTANA'S AND STATE OF NEVADA'S MEMORANDUM IN OPPOSITION TO DEFENDANT-SPECIFIC MEMORANDA ON MOTIONS TO DISMISS

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In addition to their Consolidated Memorandum, 17 Defendants filed "Defendant specific memoranda" in support of their motions to dismiss. Montana and Nevada submit this joint response to the Defendant-specific memoranda.

I. INTRODUCTION

Although Defendants have filed 17 separate Defendant-specific memoranda, for the most part, as was the case in their motion to dismiss the class action complaint ("AMCC"), little is "Defendant-specific" about the memoranda. Once again, the memoranda raise nearly identical and duplicative complaints regarding (i) non-compliance with Rule 9(b); (ii) challenges to generic and multiple-source drug theories; and (iii) the purported governmental knowledge defense. Each of these issues is also addressed by Defendants in their consolidated memorandum.

When not merely parroting "common" arguments already advanced repeatedly by some or all Defendants, each Defendant introduces a blizzard of "issues" – often in footnotes and without any citation to supporting authority – in an effort to "see what sticks." And more often than not, the "issues" raised are fact issues that should not be injected at this stage of the proceedings. In short, Defendants engage in a calculated effort to intimidate and bury the Court with reams of paper and inappropriate fact argument, seeking to distract the parties and the Court from the proper Rule 12(b)(6) standard under which the allegations in the State complaints control. The States respectfully suggest that it is important to take a step back from Defendants' blunderbuss approach and focus on common ***legal*** issues; Defendants simply should not be permitted to try this case under the guise of motions to dismiss.

This opposition first addresses the common arguments raised in virtually each of the Defendant-specific memoranda. Specific "issues" are then addressed seriatim in the order presented in the Defendant-specific memoranda.[1]

[1] Because many of the Defendant-specific arguments are repetitive, the States incorporate each preceding section in response to repetitive arguments in subsequent defendant-specific responses. This will

II. BACKGROUND OF THE COMPLAINTS

On August 1, 2003, the State of Nevada filed a 146-page, 479-paragraph Amended Complaint ("Nevada Complaint" or "NC"). To provide a backdrop for the AWP/Best Price allegations, the NC describes the distributions among drugs, generics versus brand names, and describes the various distribution channels. NC ¶¶ 89-106. The NC then describes the Medicare and Medicaid reimbursement methodologies, including the facts that Nevada reimburses at AWP minus 10% for brand name drugs (NC ¶ 114), that reimbursement is tied to AWP for generic drugs (NC ¶¶ 150-54), and that AWP is a benchmark for reimbursement in the Medicare and private payor contexts. NC ¶¶ 126, 164-72.

The NC then describes the general AWP Inflation Scheme as implemented by all Defendants. NC ¶¶ 136-75. These general allegations (*i.e.*, the how and when of the scheme) describe common, fraudulent AWP practices engaged in by Defendants. In this section, the State of Nevada details how and why the AWP scheme is applicable to generic and multiple-source drugs. NC ¶¶ 148-63. The NC then outlines the implementation of the scheme in the private reimbursement market. NC ¶¶ 164-72. Thus, consistent with the reality that this litigation applies to multiple pharmaceutical companies alleging common issues of AWP manipulation, and that Rule 8 should have meaning here, the NC and MC detail in numerous pages the manner and methods by which "all Defendants" manipulate the average wholesale price in order to effectuate over-reimbursement for their pharmaceutical products as a manner and method of doing business, and fostering the use of their products. *See* NC ¶¶ 127-76; MC ¶¶ 164-213. Although these common allegations are almost universally ignored in the Defendant-specific memoranda, those allegations expressly apply "to all Defendants."

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save the Court from 20-30 pages of repetitive responses. Defendants filed a total of 85 pages; the States respond in 58.

After describing how the contours of the AWP Inflation Scheme apply to all Defendants, the NC next sets forth 13 subsections of Defendant-specific allegations in 74 pages containing 205 paragraphs. NC ¶¶ 177-382. The Defendant-specific allegations (*i.e.*, examples of the ***how***, ***what*** and ***when*** that follow the general scheme)[2] provide examples of Defendants' wrongful conduct and in most instances examples of AWP "spreads" for the drugs at issue.

The NC also attaches an Appendix A that identifies each drug at issue, each NDC for each drug, and identifies each AWP for each of one or more of 6 one-year periods. Appendix A thus sets forth the ***what*** and ***when*** of the fraud by identifying a fraudulent AWP for each drug (by NDC number) at issue in the litigation during the time frame at issue. Appendix A does not seek to ***quantify*** the ***extent*** of Plaintiffs' damages nor the calculation of the extent of AWP manipulation. Appendix A does not attempt, therefore, to calculate the "spread" as some Defendants now demand in their motions. The Court's May 13, 2003 Order did not require identification of the spread, but required identification of the inflated AWP. So, for example, Defendant AstraZeneca, reviewing Appendix A, would be on notice for the drug Accloate, with an NDC Code of 00310-0402-60, and the fraudulent AWPs of $55.86, $59.77, $62.16, $64.66, $67.55 and $75.59, for the years 1997-2002 respectively. Each Defendant is put on notice in a similar fashion.

The State of Montana filed its Second Amended Complaint (Montana Complaint" or "MC") on August 1, 2003. The MC is organized in the same fashion as the NC. The primary difference between the complaints is that Montana named 21 Defendants, whereas Nevada named 13.[3] Thus, the MC also contains a Defendant-specific section, and Appendix A identifies examples of fraudulent AWPs for each drug at issue in the

[2] *See United States ex rel Franklin v. Parke-Davis*, 147 F. Supp. 2d 39, 46 (D. Mass. 2001) (Saris, J.).

[3] The "missing" Defendants from the Nevada complaint are Defendants in the remanded state court action.

MC. In the Defendant-specific section of the MC, the allegations typically provide examples of a Defendant's strategy of marketing the spread to increase market share.[4] And typically, this section provides examples of the estimated magnitude of the spread between reported AWP and real AWP.[5] The Defendant-specific section also often provides examples of the use of "free goods" which serves to inflate the reported AWP.[6] If there is less detail in a Defendant-specific section, this reflects a situation where a Defendant has not produced documents in response to litigation or government subpoenas.

III. COMMON ARGUMENTS REPEATED THROUGHOUT THE "DEFENDANT-SPECIFIC" MEMORANDA

A. The "No Fraudulent AWP" Argument Raised By Numerous Defendants Lacks Merit

In the Defendant-specific memoranda, some Defendants argue that the NC and MC fail to allege "a fraudulent AWP" for some or all of the drugs at issue in this case.[7] However, Defendants cannot seriously maintain there is "no fraudulent AWP" stated for every drug at issue in the complaints. Appendix A to both complaints painstakingly and clearly set forth the fraudulent AWP for each specific drug, including the NDC number.[8] Defendants cannot credibly argue that there is "no fraudulent AWP" for each drug.

Instead, Defendants' argument appears to be that for some drugs the complaints do not ***quantify the amount*** by which the fraudulent AWP exceeds true transaction amounts, or true average wholesale prices. In effect, Defendants argue that Fed. Rules 8 and 9(b) require the States to estimate damages, or to quantify the amount by which each

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[4] *See, e.g.*, MC ¶¶ 301-02, Baxter acknowledgment of practice of using the spread to increase market share and its move to increase its AWPs to meet competition. *See also* MC ¶ 304, referring to "deliberate manipulation of AWP."

[5] *See, e.g.*, MC ¶ 309 (Baxter), spreads of 369%, 813%, 205%, 368%, 437%, 650%, etc.

[6] *See, e.g.*, MC ¶ 309 (Baxter).

[7] *See, e.g.*, Abbott Mem. at 3; Aventis Mem. at 3; Bayer Mem. at 3; Glaxo Mem. at 2-3; Warrick Mem. at 3-5.

[8] The National Drug Code (NDC) is a 10-digit, 3-segment number that identifies the labeler/vendor, product (specific strength, dosage form and formulation for a particular firm) and trade package size.

published average wholesale price exceeded a good faith estimate of true transaction amounts for each drug. Defendants are wrong.

First, the complaints faithfully follow the directives of this Court's May 13 Order. Although that order applied to the class action claims, the States prepared their complaints using the guidance set forth in the May 13 Order which requires that the AMCC identify "the specific drug or drugs that were purchased from the defendant [and] the allegedly fraudulent AWP for each drug." *In re Pharm. Indus. Average Wholesale Litig.*, 263 F. Supp. 2d 172, 194 (D. Mass. 2003) ("*AWP*").

Defendants argue that the May 13, 2003 Order of this Court required ***quantification*** of the extent of AWP inflation for each drug. As pointed out in the MDL Class brief, such a requirement cannot be found in the text of the Court's Order, nor in any rule of court. *See, e.g., Treadwell v. John Hancock Mut. Life Ins. Co.*, 666 F. Supp. 278, 285-86 (D. Mass. 1987) (despite the lack of specific damage amounts, the Court stated that "[t]he precise manner in which plaintiff was allegedly harmed is a matter of proof, not pleading" and that at "the pleading stage such damages are sufficiently defined and amenable to specific proof as to be legally cognizable"); *see also Shapiro v. UJB Fin. Corp.*, 964 F. 2d. 272, 284 (3d Cir. 1992) (stating that Rule 9(b) is satisfied if the plaintiff simply alleges that "the plaintiff acted upon it to his damage"); *Grider v. Keystone Health Plan Ctr.*, 2003 U.S. Dist. Lexis 16551 (E.D. Pa. Sept. 18, 2003) (plaintiffs need not allege a specific dollar amount, and it is unlikely that they could do so without discovery). The purpose of setting forth the fraudulent AWP was, as the Court indicated, to clearly identify the precise drugs at issue in the case, coupled with the fraud being perpetrated by Defendants with respect to the designated drugs. This the States have done.

Second, only Defendants have access to the internal pricing information that would enable quantification of the extent by which a fraudulent AWP for a drug exceeds the true transaction average of wholesale prices. No Defendant makes this information

available publicly and Defendants' actual transaction, price and cost information is maintained highly confidential. Only one Defendant has, to-date, made that information available in discovery on a limited basis. Actual transaction cost and pricing information is available from no other source, and Defendants are aware of this fact. Accordingly, Defendants seek to impose a requirement that they know the States cannot meet – quantification of the extent of AWP price inflation without access to the only source of information upon which that quantification could be made, *i.e.*, Defendants' own internal cost and price information. Courts do not place a burden to quantify damages or plead detailed facts that are outside the reach of plaintiffs. *See, e.g., New England Data Servs., Inc. v. Becher*, 829 F.2d 286, 290-91 (1st Cir. 1987) (when information is beyond the grasp of the plaintiffs and within the province of defendants, a RICO claim should not be dismissed on a Rule 9(b) basis without first affording plaintiffs additional discovery providing such information).

Third, at this procedural stage the MC and NC place Defendants on notice of all of the substantive facts and claims in the case. The complaints delimit the exact drugs at issue in the proceedings and articulate the ***who*** (each of the Defendants), the ***what***, ***when*** and ***where*** (through repeated publication of purported average wholesale prices for specified drugs) and the ***how*** (the provider, PBM and other distribution chain profit incentives, undisclosed kickbacks, rebates, discounts and off invoice pricing, etc.). Each Defendant now knows which of its drugs to defend and the allegations raised against that Defendants' conduct. Furthermore, Defendants ignore that the MC and NC often contain estimates of the spread by comparing the posted AWP with estimated real AWP (*see, e.g.*, MC ¶¶ 224, 232, 311, 346, 363, 382, 418, 419, 464, 478, 521, 540, 560, 561, 601), or by comparing posted AWP with the secret cost to a wholesaler (*see, e.g.*, MC ¶¶ 226, 309, 343, 375, 401, 420, 475, 521, 541, 562). This provides an additional degree of specification that satisfies the requirements of Rule 9(b).

Defendants appear to be arguing that the anecdotal examples of AWP price spreads set forth in the text of the MC and NC should both (i) be interpreted as efforts to quantify precise AWP price inflation; and (ii) serve to delimit the price spreads, and eventual damages, that might be argued in this case for each drug. These assumptions are untrue and disclose a misunderstanding of the AWP investigations. In recent years, various public agencies have chronicled AWP price inflation by most of the Defendants in this case. In doing so, ***none*** of those agencies have had access to accurate transaction costs or pricing information. Given the absence of accurate transaction cost information from Defendants, those public agencies (and the States here) look to alternative sources of pricing information recognizing, quite explicitly, that those alternative sources of information will not give a precise quantification of AWP inflation (and, in fact, are almost always likely to yield an underestimation of price inflation). For example, the OIG – recognizing that it does not have available to it accurate transaction cost information, which information is only available from the Defendants – has used comparisons of AWP to catalog prices, wholesale price lists, and to prices available to other governmental agencies, including the Veteran's Administration, as well as to direct retail purchasers. Thus, price inflation estimation by using catalogs, federal price schedules and other rough estimates of actual transaction cost information is but ***one*** tool by which to detect manipulation of AWP price setting for the purposes of creating profit incentives to participants in the distribution chain. Resorting to these estimation tools is necessary because, without internal transaction data from pharmaceutical companies themselves, no reasonably precise calculation of the inflation is possible.

Thus, using these tools, the MC and NC, in even greater detail than the original class complaint provided, include detailed allegations of examples of the spreads for virtually each manufacturer. *See, e.g.*, Abbott, MC ¶¶ 224, 226 (spreads of 1012%, 992%, etc.); AstraZeneca, MC ¶ 258; NC ¶ 203; Aventis, MC ¶¶ 287, 293; NC ¶¶ 232, 238; Baxter, MC ¶ 309 (spreads of 226%, 369%, 813%, 650%, 649%, etc.); Boehringer,

MC ¶ 343; NC ¶ 252 (spreads of 573%, 212%, 203%, 1001%, 1066%), MC ¶ 346; NC ¶ 255; Braun, MC ¶ 359; NC ¶ 252 (757%, 1063%, 1260%); BMS, MC ¶¶ 371, 375 (spreads of 242%, 297%); Dey, MC ¶ 398 (spreads of 277%, 230%, 234%); MC ¶ 401 (spreads of 242%, 163%); MC ¶ 408 (spreads of 488%, 355%, 239%); Fujisawa, MC ¶ 418; NC ¶ 281 (spreads of 196%, 392%, 885%, 989%, 342%), MC ¶¶ 420, 422; NC ¶¶ 283, 285; Immunex, MC ¶¶ 473, 475; NC ¶¶ 294, 296 (spreads of 144%, 309%, 1003%); Johnson & Johnson, MC ¶ 490; NC ¶ 311; Novartis, MC ¶ 501; NC ¶ 322; Pharmacia, MC ¶¶ 520, 521 (spreads of 828%, 252%, 2171%, 249%, etc.); MC ¶ 526; Schering-Plough, MC ¶¶ 540-41; NC ¶¶ 341-42; and Watson, MC ¶ 601; NC ¶ 381. Defendants claim that these spreads are to be ignored, but given the allegations of the generalized scheme, and the size of these spreads, they lend strength and specificity to the allegations of AWP manipulation as to these Defendants. *See Grider*, 2003 U.S. Dist. Lexis 16551 at *49 (plaintiff need not plead the date, time or place of fraud, as long as they use some alternate means of injecting precision and some measure of substantiation). Here the detailed estimated spreads, provide an alternate means of injecting precision and substantiation.

B. Plaintiffs Have Adequately Alleged the Circumstances of the Fraud

All of the Defendants in their "specific memoranda" allege Rule 9(b) deficiencies, but their arguments lack merit.

Consistent with this Court's ruling in *United States ex rel. Franklin v. Parke-Davis*, 147 F. Supp. 2d at 46, the States have "allege[d] the circumstances of the fraud" but are "***not*** required to plead ***all*** of the evidence or facts supporting it." *Id.* at 46-47 (emphasis added); *see also id.* at 46 ("The requirements of Rule 9(b) . . . must be read in conjunction with Fed. R. Civ. P. 8(a)," which requires only a "short and plain statement of the claim."). Indeed, the Court has recognized that "where the alleged scheme of fraud

is complex and far-reaching, pleading every instance of fraud would be extremely ungainly, if not impossible." *Id.* at 49.

The *Parke-Davis* ruling is in accord with other decisions from this District, including *In re Xcelera.com Sec. Litig.*, 2002 U.S. Dist. Lexis 7400, at *7-8 (D. Mass. Mar. 8, 2002), where Judge Zobel applied Rule 9(b) and sustained plaintiffs' securities fraud claim because the complaint cited to nine investigative sources and identified and quoted from "supporting documentation to buttress the[] allegations;" and Senior Judge Caffrey's decision in *Kuney Int'l, S.A. v. Dilanni*, 746 F. Supp. 234, 237 (D. Mass. 1990), where the Court commented that Rule 9(b) is satisfied where "[t]he general outline of the general scheme to defraud . . . provides the defendant with notice of the grounds on which the plaintiff's claim is based."

Here, the "circumstances of the fraud" and the "general outline of the general scheme to defraud" are outlined in the complaints. MC, ¶¶ 164-213; NC ¶¶ 127-76. The complaints then apply these "circumstances of the fraud" to each Defendant. At the beginning of Section E of the MC, entitled "Examples of Specific AWP Inflation by Each Defendant," the States describe the specific unlawful conduct of each named Defendant in detail. MC ¶¶ 214-602; NC ¶¶ 177-382. Further, at the end of almost every Defendant-specific section, the States provide specific examples of estimated spreads, comparing prices offered to certain wholesalers to the fraudulent AWPs set forth for those drugs in industry compendia where AWPs are published. *See, e.g.*, Abbott, MC ¶¶ 224, 226 (spreads of 1012%, 992%, etc.); AstraZeneca, MC ¶ 258; NC ¶ 203; Aventis, MC ¶¶ 287, 293; NC ¶¶ 232, 238; Baxter, MC ¶ 309 (spreads of 226%, 369%, 813%, 650%, 649%, etc.); Boehringer, MC ¶ 343; NC ¶ 252 (spreads of 573%, 212%, 203%, 1,001%, 1,066%), MC ¶ 346; NC ¶ 268; Braun, MC ¶ 359; NC ¶ 268; (757%, 1,063%, 1,260%); BMS, MC ¶¶ 371, 375 (spreads of 242%, 297%); Dey, MC ¶ 398 (spreads of 277%, 230%, 234%); MC ¶ 401 (spreads of 242%, 163%); MC ¶ 408 (spreads of 488%, 355%, 239%); Fujisawa, MC ¶ 418; NC ¶ 281; (spreads of 196%, 392%, 885%, 989%,

342%), MC ¶¶ 420, 422; NC ¶¶ 283, 286; Immunex, MC ¶¶ 473, 475; NC ¶¶ 294, 296 (spreads of 144%, 309%, 1,003%); Johnson & Johnson, MC ¶ 490; NC ¶ 311; Novartis, MC ¶ 501; NC ¶ 322; Pharmacia, MC ¶¶ 520, 521 (spreads of 828%, 252%, 2171%, 249%, etc.); MC ¶ 526; Schering-Plough, MC ¶¶ 540-41; NC ¶¶ 341-42; and Watson, MC ¶ 601; NC ¶ 381. Notably, these specific allegations at times derive from documents produced by Defendants to governmental investigative sources, and are – in the words of Judge Zobel – quoted from "supporting documentation to buttress the[] allegations" of the general scheme to defraud. *In re Xcelera.com Sec. Litig.*, 2002 U.S. Dist. Lexis 7400, at *8.

The States respectfully submit that they have satisfied Rule 9(b)'s particularity requirement by clearly setting forth the "general outline of the general scheme to defraud" which is sufficient to "provide[] the defendant[s] with notice of the grounds on which the plaintiff's claim is based." *Kuney*, 746 F. Supp. at 237. In fact, Montana and Nevada have far exceeded this requirement by citing specific documents from most Defendants that directly support the AWP scheme outlined in the complaints.

And, as noted above, at this stage of the proceedings, it is not possible for the States to quantify with any greater precision than already done in the complaints, ***the specific fraudulent spread*** associated with each drug because the facts necessary to make such calculations – namely the actual wholesale transaction prices of these particular drugs and the variety of hidden incentives that Defendants employ to reduce the listed prices of drugs – are peculiarly within the Defendants' control. Indeed, as this Court recognized in *Parke-Davis*, "where facts underlying the fraud are 'peculiarly within the defendants' control,' a plaintiff may be excused from pleading the circumstances of the fraud with a high degree of precision." 147 F. Supp. 2d at 47 (quoting *Boston & Me. Corp. v. Hampton*, 987 F.2d 855, 866 (1st Cir. 1993)).[9]

[9] The States do concede that there are methods one can use to estimate the spread based on information that counsel do have, and the States can do so if required. However, the exact spread can only be alleged after review of Defendants' documents.

C. The Complaints Allege That Generic and Multiple-Source Drugs Fit Within the AWP Scheme

All Defendants but two that manufacture generic or multiple source drugs have moved to dismiss, claiming that such drugs do not "fit" within the AWP Inflation Scheme.[10] This argument is improper on a motion to dismiss because the allegations of the complaints' control. *See, e.g.*, MC ¶¶ 185-200; NC ¶¶ 138-63.

The complaints allege that for Medicare, Medicaid and private payor reimbursement, AWP is the benchmark for reimbursement of generic and multiple-source drugs. In the Medicare payor arena, multiple-source drugs or biologicals are reimbursed on the basis of AWP. For multiple-source drugs or biologicals reimbursed under Medicare Part B, the AWP is equal to the lessor of the median AWP of all of the generic forms of the drug or biological, or the lowest AWP of the brand name product. 42 C.F.R. § 405.517. MC ¶ 187; NC ¶ 150. Thus, AWP is clearly an essential ingredient of the reimbursement formula for this class of drugs.

Under the Medicaid Program, reimbursement for multiple source drugs for which there are at least three suppliers is equal to (i) a reasonable dispensing fee, plus (ii) an amount equal to 150 percent of the lowest AWP published by First DataBank, Medi-Span or the *Red Book* (an amount called the "Federal Upper Limit" or "FUL"). 42 C.F.R. § 447.332(b); NC ¶ 151; MC ¶ 162; *see also* Mont. Admin. R. 37.86.1101(3) (incorporating FULs into the definition of "maximum allowable cost" for multiple-source drugs). In Montana, if a generic drug does not have at least three suppliers, the reimbursement amount is AWP less 15%. Mont. Admin. R. 37.86.1101(1). MC ¶ 188. Again, AWP is an essential element of the reimbursement formula.

As the foregoing paragraphs allege, AWP is used in calculating reimbursement for all generic drugs. And, because reimbursement under Medicare and Medicaid is pegged to the AWP, drug makers act in unison by elevating the AWP for all generic

[10] Defendants Gensia, Inc. and Gensia Sicor have not moved to dismiss.

drugs, thereby inflating the amount of the reimbursement that occurs through Medicaid and Medicare Part B, including the Medicare co-payment through Part B. MC ¶ 189; NC ¶ 152.

The raising of an individual Defendant's reported AWP for a multiple-source drug thus raises the AWP at which the generic drug is reimbursed. In the case of Medicare, raising an individual AWP contributes to a higher median AWP. Under Medicaid, raising an individual AWP increases the FUL if the AWP being raised is the lowest AWP published (unless there are only two suppliers of the generic drug, in which case raising the AWP increases the reimbursement amount correspondingly). MC ¶¶ 189-90; NC ¶¶ 152-53.

Moreover, while any one generic manufacturer can only affect the median generic reimbursement AWP for a product (in the case of Medicare) or the FUL (in the case of Medicaid), Defendants can and do create a spread between the median AWP and the actual prices paid by reporting AWPs that are far in excess of the actual wholesale prices ***while simultaneously maintaining or lowering actual wholesale prices***. MC ¶ 191; NC ¶ 154. Thus, Defendants who argue that multiple-source drugs do not fit the paradigm of the AWP Inflation Scheme just flatly ignore these allegations which control this motion.

Indeed, contrary to Defendants' arguments, which ignore the complaints' allegations, manipulation of AWP is most pronounced in the generic context:

> Th[e] situation is more pronounced with generic drugs. Many generic companies have taken advantage of this use of AWP by substantially inflating their published AWPs. . . . [T]he system allows a retailer to acquire a drug at a low cost $2.50 per 100 tablets, for example) while relying on a published AWP ($20.00 or more) for its own pricing. It is not uncommon that the $25.00 retail price for a generic drug renders a gross profit well above $20.00 for the retailer. It is also common for the AWP of a generic product to remain stable while the actual selling price declines. . . . It is obvious that AWP is not an accurate measure of the prices manufacturers charge. It must also be noted that not all generic products will be priced

> similarly. Some, in fact, use the more traditional method of a 20% markup to reach an AWP. This can be a handicap for generic companies choosing this method because retailers often use the AWP as the starting point for many pricing decisions and an artificially high AWP provides the retailer with greater profits. [MC ¶ 192; NC ¶ 155.]

Therefore, and contrary to Defendants' argument, the MC and NC tie reimbursement for generic drugs for generic to AWP and adequately allege that Defendants were manipulating AWPs in all markets where generic drugs are sold. Defendants simply ignore all of these allegations. And in fact, documents produced by Defendant generic manufacturers show that they are aware of the AWPs reported by their competitors and of the actual sales prices of their generic competitors, and that they manipulate their own AWPs in order to gain or maintain a competitive advantage in the market for their generic products. The natural and expected result of this "leap frogging" of increasing AWPs is that multiple-source drugs have some of the highest spreads of any drugs, sometimes resulting in an AWP over 50,000% over actual costs. MC ¶ 159; NC ¶ 196. An example of this is revealed by the following chart taken from the complaints:[11]

Defendant	Multisource Drug	*Red Book* AWP	DOJ Determined Actual AWP	Percentage Spread
Abbott	Sodium Chloride	$670.89	$3.22	20,735%
Baxter	Dextrose	$928.51	$2.25	41,167%
Baxter	Sodium Chloride	$928.51	$1.71	54,199%
Boehringer Group	Leucovorin Calcium	$184.40	$2.76	6,581%
B. Braun	Sodium Chloride	$11.33	$1.49	660%
BMS Group	Etoposide (Vepesid)	$136.49	$34.30	298%
Dey	Albuterol Sulfate	$30.25	$9.17	230%
Immunex	Leucovorin Calcium	$137.94	$14.58	846%
Pharmacia	Etoposide	$157.65	$9.47	1,565%
Sicor Group	Tobramycin Sulfate	$342.19	$6.98	4,802%
Watson	Vancomycin HCL	$70.00	$3.84	1,567%

[11] *See* MC ¶ 196; NC ¶ 159.

These spreads contradict the logic of Defendants' argument that there is no AWP inflation in the generic or multi source markets, or that there is no incentive to create a spread in the generic drug reports.

Many Defendants argue that because Part B reimburses based on the median of AWP for multiple-source drugs or the lowest AWP, there is no financial incentive to inflate AWPs.[12] As noted above, the complaints allege the opposite (MC ¶¶ 189-90; NC ¶¶ 152-53), and whether these drugs fit the paradigm is an issue of fact for the jury and cannot be disposed of in the face of allegations stating the opposite.

Many Defendants also argue that where there are three or more suppliers there is no reason for AWP manipulation.[13] Again, this argument utterly ignores allegations of the complaints that are directly to the contrary. *See* MC ¶ 188-200; NC ¶¶ 151-163.

Finally, a recent lawsuit filed by generic manufacturer Dey rebuts all of Defendants' "generic and multiple source" arguments. In its complaint, Dey acknowledged that both Medicaid and private payors utilize AWP in their reimbursement. MC ¶ 198; NC ¶ 161. And Dey admits in its complaint that generic manufacturers are "cognizant of, and are highly attentive to, AWPs as reported … because of the direct relationship between the level of reimbursement … and the reported AWPs of these drugs." MC ¶ 200; NC ¶ 163. Thus Dey confirms a relationship between reimbursement and AWP, contrary to Defendants bears no relationship argument.

The reason for Dey's complaint arises from the refusal of two publishers to publish AWPs as Dey was directing. Contrary to Defendants' arguments that AWP does not matter for generics, Dey alleges the exact opposite:

> Since reimbursement to Dey's customers is, in Medicaid program in many states and in and [sic] insurance programs, ***most frequently based on the AWP as reported by the reporting services***, this arbitrary and capricious reduction by First DataBank and Medi-Span in AWP would

[12] *See, e.g.*, Baxter Mem. at 4.

[13] *See, e.g.*, Baxter Mem. at 4.

> result in a drastic reduction in the reimbursement to drug providers who choose to dispense Dey's product. ***Since there has not been a comparable reduction in the AWP for Dey's competitors, there would be no comparable reduction in the reimbursement the purchasers of competitive products receive.***
>
> Because reimbursement for Dey products would be significantly reduced, but reimbursement for those competing products would remain as they have been, Dey is prevented, by First DataBank's and Medi-Span's arbitrary and capricious acts, from effectively competing in the marketplace.
>
> ***In fact, within one day of learning that First DataBank and Medi-Span had arbitrarily changed Dey's AWP, Dey has already been contacted by at least nine of its customers complaining about the drastic changes and indicating that, because of those changes, the customers would not be able to purchase Dey products since they could not earn a reasonable profit from the sale of such products.***
>
> Further, at least one customer has already indicated that he had canceled all of his purchases presently on order from Dey and was, instead, buying those products from Dey's direct competitors.
>
> ..... These providers will cease to purchase and dispense Dey's drugs if the reimbursement for those drugs is a fraction of those obtained from competing companies. Because purchasing decisions are highly concentrated in this industry among wholesalers and group purchasing organizations, this scenario is playing out across the country and threatens to eliminate sales of Dey's products that are covered by Medicaid and insurance reimbursement programs.

¶¶ 50-54 of Dey Complaint, cited in MC ¶ 200 and NC ¶ 163 (emphasis added).

Again, these allegations, which control on this motion, defeat Defendants' argument that generics do not fit the AWP Inflation paradigm. ***Dey is admitting that without the use of inflated AWPs, like those of its competitors, it cannot compete and "within one day" of the truth being revealed, Dey was losing customers.*** Such allegations utterly belie the assertions made by all generic manufacturers that there is no economic reason to inflate AWPs on generic/multiple source drugs.

D. The Best Price Allegations Properly State Claims

Virtually all moving Defendants claim that the complaints fail to adequately allege Best Price claims and raise duplicative arguments in this regard.

First, Defendants argue that for non-innovator multiple source drugs that are rebated at AMP less 11%, there can be no Best Price claim. The States agree, and have not alleged otherwise. The complaints' Best Price claims are directed to those drugs where the rebate is tied to single source drugs and innovator multiple source drugs. It is clear that the Best Price allegations focus on those drugs. *See, e.g.*, MC ¶¶ 608-09; NC ¶¶ 388-89. Thus, Defendants did not have to spend dozens of pages creating and then attacking this AMP – 11% argument. And Defendants know which of their own drugs fall within the single source or innovator drug category and thus are on notice of the drugs at issue. To the extent they claim that the States need to specify that which Defendants already know, *i.e.*, list or identify those drugs that are single source or innovator multiple source drugs, this would be the type of make-work Rule 9(b) does not require.

Defendants next claim that the Best Price allegations fail to specify specific Best Price transgressions. The complaints adequately and specifically allege the parameters of the Best Price scheme. *See, e.g.*, MC ¶¶ 603-43; NC ¶¶ 383-412. And, at the heart of the Best Price scheme are the same type of discounts, free samples and inducements that Defendants employ in the AWP scheme. And the complaints provide examples of these devices. *See, e.g.*, MC ¶¶ 181-84, 244; NC ¶¶ 144-47, 189 (Amgen hidden rebates), MC ¶ 310 (Baxter providing free goods), MC ¶¶ 320-22 (Bayer providing free goods); MC ¶ 36; NC ¶ 270 (B. Braun offering educational grants or other value); MC ¶ 402 (Dey offering free goods); MC ¶¶ 434, 459 (GSK providing rebates); MC ¶ 476; NC ¶ 297 (Immunex providing free samples); MC ¶ 510; NC ¶ 331 (Pfizer providing unrestricted educational grants); MC ¶ 518, 523-24 (Pharmacia providing free goods); MC ¶ 544; NC ¶ 345 (Schering providing drug samples); MC ¶¶ 565; NC ¶ 336 (Sicor Group providing

free goods); MC ¶¶ 578-81 (TAP using credit memos, free goods); MC ¶ 599; NC ¶ 379 (Watson discounts). The gravamen of the Best Price allegations is that Defendants omitted these discounts, free goods and inducements when they reported Best Price, and the foregoing examples of such conduct, when combined with the general allegations, satisfy Rule 9(b).

The *LaCorte* case cited by many Defendants on the Best Price claims is distinguishable for several reasons. First, the Court acknowledged that when the facts relating to a fraud are peculiarly within the perpetrators knowledge, Rule 9(b) is relaxed. However, the Court found that the information was not in Merck's exclusive possession, it was also in the government's possession. As a result, with the government being on notice of the claim, the exclusive possession requirement was not met. *LaCorte* refused to relax the Rule 9(b) standard. Here, the Best Price offered to any provider is information exclusively within defendants' control. *LaCorte* is not applicable.

E. The "Cannot Be Deceived" Argument Does Not Apply to the State's *Parens Patriae* Claims

Defendants repeat their common argument that the States' knowledge that discounts off of AWP existed in the marketplace defeats all of the States' claims. This argument is addressed in the States' Consolidated Opposition. *See* Section II.D of Consolidated Opposition.

However, in various Defendant-specific memoranda, Defendants claim with slight variation that the States' *parens patriae* claims are also barred. There are two distinct mechanisms under which claims for consumer act violations can be prosecuted: (1) through class actions; or (2) through actions brought *parens patriae*. *In re Edmond*, 934 F.2d 1304, 1311 (4th Cir. 1991). Class certification is specifically not required for *parens patriae* cases. *Id.* at 1313.

The purpose of the *parens patriae* action in the consumer context is to fill the gap created by the difficulties of gaining class certification and managing class actions once

certified. *In re Grand Jury Investigation of Cuisinarts*, 516 F. Supp. 1008, 1014-15 (D. Conn. 1981); *see also State by Humphrey v. Ri-Mel, Inc.*, 417 N.W.2d 102, 112 (Minn. Ct. App. 1987) (citing *State of Minnesota v. Standard Oil Co.*, 568 F. Supp. 556, 563 (D. Minn. 1983)) (noting states have incentive to bring actions as *parens patriae* to assure citizens the full benefit of legislation because individuals with small overcharges would likely not avail themselves of their individual remedy because of the burden of pursuing the action). The *parens patriae* provision is especially important given that the private right of action under the consumer protection act in Montana and Nevada expressly excludes class actions. *See, e.g.*, Mont. Stat. Sec. 30-14-133.

Furthermore, the test for whether conduct violates the States' consumer protection law is whether the Act has the capacity to deceive as applied to the mind of the typical consumer, not a consumer fraud expert or a State Medicaid official. This premise would not be seriously disputed in a typical class action with a consumer serving as class representative, and the State, when serving as *parens patriae*, in effect wears the hat of the consumer.

Hence, in the *parens patriae* context, the States' knowledge with respect to AWP manipulation is irrelevant to the *parens patriae* claims. The standard remains the same, *i.e.*, does the practice have the capacity to deceive the "less sophisticated consumer." *Jeter v. Credit Bureau*, 760 F.2d 1168, 1172-1175 (11th Cir. 1985). Capacity to deceive, rather than actual deception, is the primary criterion for establishing whether a particular type of conduct amounts to misrepresentation. *In the Matter of Grolier, Inc.*, 91 F.T.C. 315, 430 (1978); *Mohawk Refining Corp. v. FTC*, 263 F.2d 818, 821 (3rd Cir. 1959). Neither intent to deceive nor actual deception is required. *Dwyer v. J.I. Kislak Mortgage Corp.*, 103 Wn. App. 542, 547, 13 P.3d 240 (2000), *review denied*, 143 Wn.2d 1024 (2001). Thus, contrary to Defendants' arguments, the States' purported knowledge has no bearing on the *parens patriae* claim. Nothing in the MC or NC, or the record before

the Court, suggests that the practices described in the complaints did not have the capacity to deceive consumers.

IV. ARGUMENT – DEFENDANT SPECIFIC

Plaintiffs now turn to a Defendant by Defendant response, incorporating by reference each response so as to avoid repetition.

A. Abbott

1. Review of Abbott allegations

In the MC, the State alleges specific facts against Abbott Laboratories ("Abbott"). *See* MC ¶¶ 216-23.

These allegations begin by citing to internal Abbott documents evidencing Abbott's direct efforts to maximize the "bigger spread between AWP and cost" and that Abbott routinely engaged in "spread shopping." MC ¶ 220-22. Based upon documents only recently uncovered, the MC further provides details of enormous spreads on Abbott drugs. MC ¶¶ 224-26. And it does so for dozens of drugs, with spreads repeatedly as high as 900-1,000% for amino acids; 300-400% for liposyn products; 200-400% for acyclovir sodium products; 500-700% for cimetide hydrochloride products; 240-832% for dextrose products; 140-445% for Heparin; and the MC lists many more such examples. MC ¶ 226. Each of these spreads identifies the published AWP and the secret wholesale cost. There are no allegations that Montana or its citizens were aware of the magnitude of these spreads.

The complaint outlines government investigations targeting AWP abuse for Abbott's vancomycin and the DOJ's identification of 16 drugs for which 2001 reported AWPs were substantially higher than the DOJ determined actual AWP. MC ¶¶ 227-33. (*E.g.*, spreads of 697%, 6,037%, 1,304%, 12,531%, 20,735%). There is no allegation in the complaint that Montana or its citizens were aware of these allegations.

2. The Abbott-specific arguments lack merit

a. Rebate claims for brand name and innovator multiple-source drugs are appropriate

Abbott argues that the allegations concerning Best Price fail because if Abbott failed to report discounts and other price reductions, such misreporting would increase the rebates, not decrease them. This is nonsensical. As noted above, the complaint alleges that the Best Price is to be the lowest price at which a drug is offered, including all discounts, free goods and other cost reducers. MC ¶ 609. The complaint alleges that Abbott did not report the Best Price, by virtue of not including in Best Price free goods and other cost reducers, thereby resulting in a smaller rebates than warranted. MC ¶ 612. This states a claim for a violation of Abbott's Best Price obligations.

b. Multiple-source and generic drugs are alleged to be part of the AWP scheme

The States have already responded to Defendants' challenge regarding "single source" and innovator multiple source drugs. *See* Section III.C. And, as to Abbott, the MC provides examples as to how Abbott abused the AWP system with respect to its generic drugs. *See, e.g.*, MC ¶ 224 (spreads of 6,037%; 15,671%; 20,735%); MC ¶ 226 (identifying examples of Abbott's use of generics in the AWP scheme); and MC ¶ 232. Though Abbott claims that competition based on alleged AWP manipulation makes no sense, the huge spreads identified in the MC belie that notion, as do other allegations regarding Abbott in the MC. *See* MC ¶¶ 189-200. Abbott criticizes Montana because the "state never identifies which drugs are multiple-source and precisely which drugs are paid under each reimbursement methodology." Abbott Mem. at 3. Of course, Abbott, as the manufacturer, knows itself which drugs are multiple-source, so this demand is downright silly. As to which drugs are reimbursed under various methodologies, the complaint alleges that AWP is the benchmark for reimbursement of the drugs at issue and the entire focus of the complaint is on AWP. *See, e.g.*, MC ¶¶ 164-72. Therefore, the flat rate situations Abbott refers to are not within the transactions at issue in the complaint,

and the complaint alleges that all drugs in the MC were reimbursed both in the Medicare, Medicaid and private markets based in part on AWP. MC ¶¶ 164-72.

c. Montana's knowledge is not a defense in this motion

Abbott raises the State's knowledge defense which has been addressed elsewhere. *See* Consolidated Opposition at II.D, Section III,E, *infra*. Abbott argues that Montana could have performed a reverse calculation using Abbott's unit rebate amount ("URA") to arrive at Abbott's AMP, and then used the AMP information to divine the true and correct pricing information that Abbott should have reported in the first instance but intentionally did not. Abbott Mem. at 3-4. Thus, Abbott's argument is akin to: "Ok, so I lied when reporting AWPs in order to create spreads that promoted my products at the expense of the Medicaid program, but I also gave the federal government other information that should have enabled the State to, inferentially, detect my lie." This argument is specious for several reasons.

First, it ignores the controlling allegations that Montana did not know the truth due to fraudulent concealment. MC ¶¶ 635-43. Second, even if Montana could have performed this calculation each and every quarter for every Abbott drug, it still does not yield the AWP because AMP is the average price paid to the manufacturer, whereas AWP is the average price paid to the wholesaler; thus, it is not an "apples-to-apples" comparison. In any event, Abbott's argument regarding URAs is, in effect, a "back door" attempt to assert the affirmative defense of estoppel, which is not available to Abbott as a matter of law. *See, e.g., Chennault v. Sager*, 610 P.2d 173, 176 (Mont. 1980); Consolidated Opp. at Section II.D.1. And Defendants cite no authority for the proposition that a party is barred from pursuing claims for failure to make a complicated mathematical sleuthing exercise to discover the misconduct of a defendant. At best, the question whether Montana should have discovered that Abbott was providing false Best Price information to the federal government, and thus somehow limited its damages, is a

jury question. *See* Consolidated Opp. at Section II.D.4. And notably absent from Abbott's argument is any evidence that Montana's citizens knew, and thus no argument has been made as to the State's *parens patriae* claims. *See* Section III.E., *supra*.

d. The fraudulent AWP is identified

The parties have elsewhere briefed the issue of whether Appendix A's identification of AWPs complies with the Court's May 13 order and Fed. R. Civ. P. 9(b). Abbott not only repeats this argument, it also claims in its Defendant "specific" brief that the complaint's detail about Abbott's spreads establish nothing.

Abbott ignores the fact that the spreads alleged in MC ¶¶ 224 and 226 follow a detailed outline of the AWP Inflation Scheme that identifies how Abbott and others used discounts, grants and other hidden devices to lower the cost to providers. The detailed spreads in the MC are allegations adding specifics to the scheme. Contrary to Abbott's argument that this detail "provides nothing," a complaint is not a trial. The purpose of the complaint is to provide Abbott notice, and the dozens of examples of enormous spreads properly put Abbott and other Defendants on notice that these drugs and these spreads are alleged to be involved in the AWP scheme. And Montana has pointed to more than a spread; it has quoted internal Abbott documents evidencing a willingness to play the spread game, a game which the Office of Inspector General has declared to be illegal. MC ¶¶ 220-22, 231. It is for the jury to decide if these spreads mean "nothing." At the present, in the context of a complaint, the spreads provide substantiation as to AWP manipulation. The MC alleges that the defendants "fabricated and overstated their AWPs." MC ¶ 136. The Abbott spreads, of 1,104%, 423%, 1,012%, 1,356%, 1,191%, certainly can be reasonably taken by the trier of fact to mean something, namely the fabrication alleged in the complaint. MC ¶¶ 224-26.

e. Plaintiffs were not required to name a competitor

Abbott also complains that the MC does not "identify a competitor against whom four single source drugs . . . compete on the 'alleged spread.'" Abbott Mem. at 5. This issue was briefed as to the AMCC, and Montana refers to that briefing.

B. Amgen

1. Review of Amgen allegations

The complaints outline the general AWP scheme under which all Defendants operated. *See, e.g.*, MC ¶¶ 164-200; NC ¶ 127-63. And the complaints delineate how the AWP scheme impacts the Medicaid, generic and price markets. *Id.* The complaints detail Amgen's focus on payor reimbursement policies (MC ¶ 239; NC ¶ 184), outline hidden incentives Amgen provided for EPO (MC ¶¶ 243-46; NC ¶¶ 188-91), and allege that Amgen refused to disclose to the OIG information which would have revealed secret rebates. MC ¶ 247; NC ¶ 192.

2. The Amgen-specific arguments lack merit

The main thrust of Amgen's specific argument is that the States' allegations may only be read to ascribe "guilt by association" to Amgen. This is not the case. The complaints allege that Amgen – a manufacturer that focuses on a few products all of which are reimbursable under Medicare Part B – systematically inflates the AWP for each of its few drugs in order to create profit incentives to providers for others in the drug distribution chain. Competitors for each of those drugs are identified because, as a matter of historic fact, Amgen has gone toe-to-toe with these manufacturers (sometimes in highly acrimonious ways) to compete for market share, and in doing so has used the tool of AWP inflation (as has also been the case with its competitors). MC ¶ 240; NC ¶ 185. And the GAO has reported that Epogen accounted for the second highest percentage of Medicare reimbursement and, unlike most of the Defendants, Amgen refused to provide GAO with information regarding rebates. MC ¶¶ 247-48; NC ¶¶ 192-93. It is not unreasonable to infer from the information generally available, that disclosure of the

rebates would have revealed AWP manipulation, and that is why Amgen did not provide the information to the GAO.

Moreover, while Amgen attacks the "logical inference" that Amgen has engaged in over-reimbursement as a corporate-wide mechanism to gain market share, Amgen ignores that it has endorsed this corporate practice and acknowledged it in litigation regarding its over-reimbursement policies. In *Amgen, Inc. v. Scully*, 234 F. Supp. 2d 9 (D.D.C. 2002), Amgen filed suit against HHS attacking a proposed HHS rule that would take reimbursement for Amgen's Aransep out of the AWP system and put it into a direct "pass-through" regime. The proposed regulation would not, of course, inhibit Amgen in any way with respect to the actual prices it could charge its customers. Nor did it affect Amgen's customers' ability to negotiate actual purchase prices with Amgen. Instead, the proposed regulation simply would affect the manner in which Amgen's customers would be reimbursed by Medicare for their Aransep purchases. (Meanwhile, one of Amgen's archrivals, Ortho Biotech Products, LP, a subsidiary of Johnson & Johnson and manufacturer of Procrit, also sought to intervene in the case; it, too, saw a significant competitive edge to seeking to enforce the proposed regulation which would give Amgen a disadvantage, and Ortho an advantage, in marketing the spread for reimbursement dollars in this competitive therapeutic category). Amgen argued that it nevertheless had standing to complain.

The *Amgen* court rejected Amgen's argument, stating that it "appears to the Court that the interest plaintiff [was] seeking to protect is its own competitive interest in financial gain." *Id.* at 21. The Court then cited to *TAP Pharms. v. United States HHS*, 163 F.3d 199 (4th Cir. 1998) (in which TAP, the manufacturer of Lupron who eventually paid $875 million for its abusive trade pricing practices, attacked proposed HHS reimbursement charges for Lupron), and observed that Amgen's arguments – in an effort to protect its over-reimbursement marketing strategies – were identical to the interests that TAP sought to protect in *TAP Pharmaceuticals*:

> Like the drug manufacturer plaintiff in *TAP Pharmaceuticals,* Amgen asserts an interest in enforcing a statutory provision that purportedly sets the Medicare payment rate for a particular pharmaceutical product on the basis of 95 percent of the average wholesale price of that product, and not on the basis of the Medicare payment rate for a competing pharmaceutical product. Like the plaintiff in *Tap Pharmaceuticals,* ***Amgen is asserting purely commercial interests in increasing its revenues and preventing loss of market share to its competitor.*** Like the plaintiff in *TAP Pharmaceuticals,* Amgen is neither a beneficiary of the Medicare statute nor a competitor of an entity that is regulated by that statute. . . Since its purely commercial interest in the sale of Aransep does not place it "in the same position as a member" of the beneficiary group or "a commercial competitor of such a member," Amgen, like the plaintiff in *TAP Pharmaceuticals*, cannot satisfy the prudential standing requirements imposed by the APA. [*Amgen*, 234 F. Supp. 2d at 24.] [Emphasis added.]

Amgen also eschews the importance of the 1993 study regarding Epogen reimbursement conducted by HHS, but these are (again) disputed issues of fact. Amgen Mem. at 2. In any event, the 1993 HHS Report, as well as a follow-up report of HHS in late 1997, both state that "ESRD [end stage renal disease] facilities purchased EPO at a rate substantially less than the current Medicare reimbursement of $10 per 1,000 units," and that (even though Amgen repeatedly refused to provide sales and revenue figures) estimates of after-rebate costs to dialysis facilities were increasingly, and markedly, below the Medicare reimbursement rate. When those after-rebate costs are compared to the AWP posted by Amgen for EPO, one can determine that AWP-based end-payors (third party payors or cash paying consumers) are paying markedly more for EPO, even if one flexibly interprets the AWP for EPO. The over-reimbursement of EPO for Amgen, and the consequent market share and profits to Amgen, were so large that the 1993 report detailed the ever-increasing profit margins of Amgen as one reason to revisit the Epogen reimbursement rate. In short, the allegations – not Amgen's factual denial of them – control in the 12(b)(6) context.

Referring to Rule 9(b), Amgen complains that the States fail to identify a single spread as to its drugs. But of course Amgen has refused to disclose its spread to